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April 5, 2004

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Art Unit: 1631
Examiner: M.A. Moran
Conf. No.: 8785

Re: U.S. Patent Application Serial No. 09/815,264 filed March 23, 2001
Inventors: Andrey A. BOUKHAROV *et al.*
Title: Genomic Plant Sequences and Uses Thereof
Atty. Docket: 16517.006

Sir:

Transmitted herewith for appropriate action by the U.S. Patent and Trademark Office (PTO) are the following documents:

1. Appellant's Brief (in triplicate), with attached Appendix A; and

2. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

Authorization is hereby given to charge the statutory fee of $330.00 for filing Appellant's Brief to Arnold & Porter LLP Deposit Account No. 50-2387, referencing docket number 16517.006. A duplicate copy of this letter is enclosed.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe any additional fees are due in conjunction with this filing. However, if any fees under 37 C.F.R. § 1.16 or § 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter LLP Deposit Account No. 50-2387, referencing docket number 16517.006. A duplicate copy of this letter is enclosed.

Sincerely,

David R. Marsh (Reg. No. 41,408)
Holly Logue Prutz (Reg. No. 47,755)

Enclosures

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:			
Andrey A. BOUKHAROV *et al.*		Art Unit:	1631
Appln. No.:	09/815,264	Examiner:	Marjorie A. Moran
Filed:	March 23,2001	Atty. Docket:	16517.006
For:	Genomic Plant Sequences and Uses Thereof	Confirmation No.	8785

APPELLANT'S BRIEF

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

This is an Appeal from the Final Rejection of all claims pending in the above-captioned patent application. A Notice of Appeal was filed on February 5, 2004. Authorization to charge the official fees for this filing is given in the accompanying transmittal letter. *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

Appellant is unaware of any Appeals or Interferences related to this Appeal.

3. Status of Claims

Claims 1-5, 8-11, 38 and 39 are pending. Claims 1-5, 8-11, 38 and 39 stand finally rejected under 35 U.S.C. §§ 101 and 112, first paragraph. Appellant appeals all of the rejections of claims 1-5, 8-11, 38 and 39.

4. Status of Amendments

Appellant has not filed any responses subsequent to Final Rejection in this case.

5. Summary of Invention

The invention is directed to a substantially purified nucleic acid molecule comprising a nucleic acid sequence where the nucleic acid sequence hybridizes under stringent conditions with a sequence of SEQ ID NO: 1 or a complement thereof. Specification at page 5, lines 15-18. The invention is also directed to a substantially purified nucleic acid molecule comprising a nucleic acid sequence where the nucleic acid sequence exhibits 85% or greater identity to a sequence of SEQ ID NO: 1. Specification at page 5, lines 15-20. The invention is also directed to a substantially purified nucleic acid molecule comprising a nucleotide sequence of SEQ ID NO: 1 or a complement thereof. Specification at page 11, line 23 to page 12, line 3. The invention is also directed to a substantially purified nucleic acid molecule consisting of a nucleotide sequence of SEQ ID NO: 1 or a complement thereof. *Id.*

6. Issues

The issues in this Appeal are:

(a) whether claims 1-5, 8-11, 38 and 39 are unpatentable under 35 U.S.C. § 101 for allegedly being unsupported by a specific asserted utility or a well established utility; and

(b) whether claims 1-5, 8-11, 38 and 39 are unpatentable under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement because the claimed invention purportedly lacks utility.

7. Grouping of Claims

Claims 1-5, 8-11, 38 and 39 remain in this case. Claims 1, 38 and 39 are independent. All of the claims at issue do not stand or fall together. The separate patentability of claims 1-5, 8-11, 38 and 39 is addressed in Sections 8.A through 8.C below. A copy of the claims on appeal is attached hereto as Appendix A.

8. Argument

A. Summary of Appellant's Position

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility....where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met their part of the bargain – they have disclosed nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example use as a promoter. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit. Because the claimed nucleic acid molecules provide at least these benefits, they satisfy the utility requirement of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed nucleic acid molecules for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

B. The Claimed Nucleic Acids Have Legal Utility

Claims 1-5, 8-11, 38 and 39 stand rejected under 35 U.S.C. § 101 as allegedly not supported by a "specific, substantial, and credible utility or, in the alternative, a well-established utility." Final Action mailed November 5, 2003 ("Final Action"), at page 2.

The rejection is based upon two basic premises. First, while the Examiner admits that the asserted uses as a promoter are specific uses, these are allegedly not substantial uses as requiring further characterization to identify or confirm such uses. Final Action at pages 2-3. Second, the Examiner asserts that the additional asserted uses "are all uses

applicable to any nucleic acid and are not specific, substantial and credible" to the claimed sequences. *Id.*, at page 4.

This analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson*. The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip*, 185 F.3d at 1366, 51 USPQ.2d at 1702. For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

Applicants have asserted in the specification that the claimed nucleic acid molecules provide identifiable benefits, for example, use as a regulatory region or promoter. *See, e.g.*, specification at page 28 line 15 through page 29, line 10. The specification also asserts other uses for the claimed nucleic acid molecules, for example,

use to identify the presence or absence of a polymorphism, use a genetic markers and in microarray-based methods for high-throughput screening of plant genomic DNA. *See, e.g.*, specification at page 58 line 9 through page 65, line 8, page 49, line 1 to page 54, line 10 and page 128, line 17 to page 132, line 10. Any of these utilities described alone is enough to satisfy Section 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the premise of the rejection under Section 101 is incorrect, and the rejection should be reversed.

(1) The Claimed Nucleic Acid Molecules Provide A Specific Benefit, *i.e.*, They Have Specific Utility

The Examiner admits that the specification describes a specific utility for the claimed nucleic acid molecules. Final Action, at page 3. The Examiner acknowledges that uses as promoters "is not a utility that can be applied to all nucleic acids" *Id.* at 3. Moreover, as Appellant has previously pointed out, the specification also discloses additional utilities for the claimed nucleic acid molecules,[1] including as a marker in genetic mapping[2], to isolate promoters, to identify polymorphisms, and as a probe or primer. Specification at page 54, line 11 through page 58, line 4, page 58, lines 5-8, page 58 line 9 through page 65, line 8 and page 38 line 17 through page 40, line 4. Other utilities disclosed in the specification include use of the claimed nucleic acid molecules to

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[1] It is irrelevant whether the corresponding mRNA or polypeptide have utility because Applicants are not relying on utility of the mRNA or polypeptide to establish utility of the claimed nucleic acid molecules.

[2] One can use the claimed nucleic acid molecules to determine location of a corresponding DNA sequence on a physical map or genetic map location without knowing anything beyond the claimed sequence. The use of molecular markers is a practical activity in the development of nutritionally enhanced or agriculturally enhanced crops. Such markers are useful in, for example, genetic mapping or linkage analysis, marker-assisted breeding, physical genome mapping, transgenic crop production, crop monitoring diagnostics, and gene identification and isolation. As more markers are identified, genetic maps will become more detailed and it will be easier for plant breeders to breed for particular traits.

measure the level of mRNA in a sample[3]. *See*, specification at page 65 line 9 through page 67 line 7.

(a) Identifying the Presence or Absence of a Polymorphism

More particularly, one of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Specification at page 58 line 9 through page 65. The Examiner argues that this utility, like many of the asserted utilities, is "applicable to any nucleic acid and [is] not specific, substantial and credible for SEQ ID NO: 1." Final Office Action at page 4. However, the Examiner does not provide any support (legal or factual) for the proposition that the asserted uses, for example detection of polymorphisms using the claimed nucleic acid molecules, are not legal utilities.

Many of the disclosed utilities in this case, including the detection of polymorphisms, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. The fact that, *e.g.*, a new and nonobvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such "tools" have legal utility. "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107 at page 2100-33.

Use of the claimed nucleic acid molecules to detect the presence or absence of polymorphisms is no more legally insufficient than using a gas chromatograph to analyze

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[3] It is standard practice to screen populations of nucleic acids with nucleic acid sequences attached to a microarray, without characterizing each and every target mRNA. Knowing that the gene corresponding to the claimed nucleic acid molecules is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect expression changes in traits of interest.

the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself. Information has been obtained about the gas.[4] Likewise, the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

The claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit, to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acids, not from the use of other molecules. Moreover, the Examiner has even admitted that at least one use, as a promoter, is a specific utility. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101.

(b) Probes for Other Molecules or Source for Primers

Other uses for the claimed nucleic acid molecules are as probes for other molecules or as a source of primers. The specification discloses that the claimed nucleic acid molecules can be used to isolate nucleic acid molecules of other plants and organisms such as maize, sorghum, barley and wheat.[5] *See, e.g.*, Specification at page

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[4] For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

[5] Furthermore, one skilled in the art of hybridization and amplification understands how to design and utilize probes and primers to target a sequence of interest, and therefore it is not necessary for Applicants to provide a laundry list of each and every nucleic acid molecule that can be identified using the claimed nucleic acid molecules.

57, line 5 through page 58 line 8. The Examiner has not provided any evidence that would reasonably suggest that this cannot be done, and thus has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).

Applicants have specifically disclosed that one use of the claimed nucleic acid molecules is use as a promoter or regulatory element. *See, e.g.*, Specification at page 15, line 17 through page 21, line 12. The Examiner denigrates the additional asserted utilities utility by arguing that the uses "are all applicable to any nucleic acid and are not specific, substantial and credible for SEQ ID NO: 1." Final Office Action at page 4. In short, the Examiner suggests that these additional asserted utilities are legally insufficient simply because other molecules can be used for the same purpose, *e.g.*, as markers. That position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result…"). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Moreover, it is factually incorrect that this use is not "specific" to the claimed nucleic acid molecules. The claimed nucleic acid molecules provide a particularly appropriate and demonstrably useful to isolate a syntenic promoter in, for example, maize

or barley. A random nucleic acid molecule does not provide an equally good starting point to isolate such a promoter. Furthermore, even if a random nucleic acid molecule provided a better starting point than the claimed nucleic acid molecules, it would not obviate the utility of the claimed nucleic acid molecules. An invention may be "less effective than existing devices but nevertheless meet the statutory criteria for patentability." *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12, 1 U.S.P.Q.2d 1196, 1199 n.12 (Fed. Cir. 1986).

The Examiner has failed to provide evidence, or even to suggest a reason for believing that the claimed nucleic acid molecules could not be so used. Accordingly, the assertion of this utility as a probe for other molecules or as a source of primers satisfies the requirements of 35 U.S.C. § 101. *See In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995).

(2) The Claimed Nucleic Acid Molecules Provide Practical, Real World Benefits, *i.e.*, They Have Substantial Utility

As previously stated the Examiner argues that the disclosed utility as "a promoter or regulatory element, while specific, is not a substantial utility" for the claimed sequence. Final Action at page 2. The basis of the Examiner's assertion is that "further characterization of the claimed subject matter would be required to identify or reasonably confirm a 'real world' use...." *Id.* at pages 2-3. The touchstone of "substantial" utility is "real world" or "practical utility." *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). " 'Practical utility' is a shorthand way of attributing 'real world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (C.C.P.A.

1980) ("tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use").[6]

There can be no question that one skilled in the art can use the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, for example as a promoter or regulatory element. The use as a promoter or regulatory element provides an immediate benefit to the public because, for example, it enables methods of promoting and regulating expression of structural nucleic acid sequences in a host cell. *See*, specification at page 32 line 18, through page 34 line 16. This use as a promoter provides, for example, the enhancement of plants and seeds "to have desirable agricultural, biosynthetic, commercial, chemical, insecticidal, industrial, nutritional, or pharmaceutical properties." *See, e.g.*, specification at page 2, lines 5-10. Such use provides an immediate benefit and thus a practical utility to the public. The Examiner has provided no support (legal or factual) that the allegation that the claimed nucleic acid molecules can not be used for the asserted utilities.

(3) The Disclosed Utilities Are Credible to One of Skill in the Art

An assertion of utility must be accepted by the Examiner unless it would not be considered "credible" by a person of ordinary skill in the art. MPEP § 2107 at 2100-29. Cases in which utility was found not to be credible are rare, and usually involve "hare-brained" utilities.[7] A challenge to the credibility of a utility is essentially a challenge

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[6] *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (C.C.P.A. 1974).

[7] Examples of incredible utilities are given in MPEP § 2107 at page 2100-34, and include:

> an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 U.S.P.Q. 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 U.S.P.Q. 1340 (Fed. Cir. 1989)), a flying machine operating on "flapping or flutter function" (*In re Houghton*, 433 F.2d 820, 167 U.S.P.Q. 687 (C.C.P.A. 1970)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 U.S.P.Q. 221 (C.C.P.A. 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 U.S.P.Q. 516 (C.C.P.A. 1963)), a method of

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directed to operability, and such a challenge must be supported by a clear statement of "factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 2107 at 2100-41.

Applicants have explicitly identified specific and substantial utilities. "To violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992). To date, the Examiner has provided no evidence that the claimed nucleic acid molecules will not work for the disclosed utilities. Unless and until the Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn.

In view of the above, the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 1-5, 8-11, 38 and 39 under 35 U.S.C. §101 is improper and should be reversed.

C. The Claimed Nucleic Acids Are Enabled by the Specification

The enablement of the claimed nucleic acid molecules has been challenged. Claims 1-5, 8-11, 38 and 39 were rejected as not enabled by the specification, because the claimed nucleic acid molecules allegedly lack utility and therefore cannot be enabled. Final Action at page 5. This rejection is erroneous and has been overcome by the

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controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 U.S.P.Q. 221 (C.C.P.A. 1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 U.S.P.Q. 609 (C.C.P.A. 1969)).

arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

Date: April 5, 2004

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APPENDIX A

1. A substantially purified nucleic acid molecule comprising a nucleic acid sequence wherein the nucleic acid sequence:

i) hybridizes under stringent conditions with a sequence of SEQ ID NO: 1 or a complement thereof; or

ii) exhibits an 85% or greater identity to a sequence of SEQ ID NO: 1.

2. The nucleic acid molecule of claim 1, wherein the nucleic acid sequence exhibits a 90% or greater identity to a nucleic acid sequence of SEQ ID NO: 1.

3. The nucleic acid molecule of claim 1, wherein the nucleic acid sequence exhibits a 95% or greater identity to a nucleic acid sequence of SEQ ID NO: 1.

4. The nucleic acid molecule of claim 1, wherein the nucleic acid sequence exhibits a 99% or greater identity to a nucleic acid sequence of SEQ ID NO: 1.

5. The nucleic acid molecule of claim 1, wherein said nucleic acid sequence comprises a sequence of SEQ ID NO: 1.

8. The nucleic acid sequence of claim 1, wherein the nucleic acid molecule further comprises one or more cis-acting nucleic acid elements.

9. The nucleic acid molecule of claim 1, wherein the nucleic acid molecule further comprises a 5' leader sequence selected from the group consisting of dSSU 5', PetHSP70 5', and GmHSP17.9 5'.

10. The nucleic acid molecule of claim 1, wherein the nucleic acid molecule further comprises a 3' untranslated region.

11. The nucleic acid molecule of claim 10, wherein the 3' untranslated region is selected from the group consisting of NOS 3', E9 3", ADR12 3', 7Sα 3', 11S 3', and albumin 3'.

38. A substantially purified nucleic acid molecule that comprises a nucleotide sequence of SEQ ID NO: 1 or a complement thereof.

39. A substantially purified nucleic acid molecule that consists of a nucleotide sequence of SEQ ID NO: 1 or a complement thereof.